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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,682	08/03/2006	Daniel W. Mayer	MCN226USPT02	4858
23403 7590 04/30/2008 SHERRILL LAW OFFICES 4756 BANNING AVE SUITE 212 WHITE BEAR LAKE, MN 55110-3205			EXAMINER GISSEL, GUNNAR J	
			ART UNIT 2856	PAPER NUMBER
			MAIL DATE 04/30/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,682	<b>Applicant(s)</b> MAYER ET AL.	
	<b>Examiner</b> Gunnar J. Gissel	<b>Art Unit</b> 2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/20/2007 05/24/2007 03/27/2007 11/07/2006</u> . | 6) <input type="checkbox"/> Other: ____.  |



## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. It is not clear whether the invention is directed to the *system* comprising a needle, mass flow rate sensor, vacuum pump and a hermetically sealed package, or, as the claims indicate, the *device* comprising a needle, mass flow rate sensor and vacuum pump. In claim 1, "the lumen defined by the needle for evacuating gas," seems to indicate an intended use of the needle, mass flow rate sensor and vacuum pump device, and not necessarily require the hermetically sealed package. In claim 2, "the lumen defined by the needle for evacuating gas," and "the oxygen sensor for permitting sensing of oxygen concentration of the sample," similarly seems to indicate a use, rather than a claimed aspect of the invention.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,212,993 to William Mayer (Mayer) with teachings from US Patent 5,203,822 to Gunter Gurich et al. (Gurich).

6. Regarding Claims 1, 2, Mayer discloses an instrument comprising a needle having a lumen (Mayer, needle having a lumen 12); a vacuum pump which is in fluid communication with the lumen defined by the needle (Mayer, vacuum pump 30) for evacuating gas from a hermetically sealed packaging (Mayer, column 1, lines 7-9); an oxygen sensor in sealed fluid communication with the lumen defined by the needle (Mayer, oxygen sensor 18). Mayer also teaches that the oxygen sensor is in operable contact with the gas that flows from the package through the lumen (Mayer, figure 2). Mayer does not explicitly disclose a mass flow rate sensor in sealed fluid communication with the needle's lumen.

7. Gurich discloses a mass flow rate sensor in sealed fluid communication with the lumen defined by the needle (Gurich, mass flow sensor 3). Gurich further discloses that the mass flow rate sensor is in sealed fluid communication with the vacuum pump, such that mass flow is directed from the evacuated packaging into operable contact with the mass flow rate sensor (Gurich, column 3, lines 12-23). Gurich discloses a mass flow rate sensor that is positioned in the flow path from a higher pressure area to a lower pressure area. In the case of Gurich, and Applicant's claim, the high pressure area is the area of interest, and the low pressure area is ultimately the exhaust.

8. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Mayer with teachings from Gurich because the refinements in

Gurich allow for the detection of leakage despite differing, changing or otherwise inconsistent pressure in the body of interest (column 3, lines 15-20).

Regarding Claims 3 and 4, Mayer discloses selecting a hermetically sealed packaging (Mayer, figure 2, package 40); puncturing the hermetically sealed packaging with a hollow needle having a lumen (Mayer, needle having a lumen 12); pumping a sample of the gas within the hermetically sealed packaging through the lumen of the needle and into operable contact with an oxygen sensor for sensing the oxygen concentration in the sample (Mayer, oxygen sensor 18); evacuating any gaseous content from within the hermetically sealed packaging through the lumen of the needle to form a vacuum within the hermetically sealed packaging (Mayer, vacuum pump 30); but does not explicitly disclose a mass flow rate meter.

Gurich discloses and measuring mass flow rate from within the evacuated hermetically sealed packaging, whereby a mass flow rate (Gurich, mass flow rate sensor 3) from the evacuated hermetically sealed packaging above a threshold value indicates a leak in the hermetically sealed packaging (Gurich, columns 3, lines 12-25).

It would have been obvious to one of ordinary skill to combine Mayer's invention with teachings from Gurich because the refinements in Gurich allow for the detection of leakage despite differing, changing or otherwise inconsistent pressure in the body of interest (column 3, lines 15-20).

### ***Double Patenting***

9. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,252,014. Although

Art Unit: 2856

the conflicting claims are not identical, they are not patentably distinct from each other because Applicant's device comprises a needle, mass flow rate sensor and vacuum pump, in a specific configuration, all of which are also required in US Patent 7,252,014.

10. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4 of copending Application No. 20070289390. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a needle having a lumen, a mass flow rate sensor and a vacuum pump in fluid communication with the mass flow rate sensor.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claim 2 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,252,014 in view of US Patent 5,212,993 to William Mayer (Mayer). Both Applicant's patent and application claim a needle having a lumen, a mass flow rate sensor in sealed fluid communication with the lumen and a vacuum pump in communication with the lumen. Applicant's patent does not claim an oxygen sensor, as the application does, but it would have been obvious to one of ordinary skill in the art at the time of the invention to add an oxygen sensor to a package integrity tester, as Mayer did (Mayer, figure 2, sensor 18), because it is conventional to test the oxygen leakage in packaged food (Mayer, column 1, lines 35-40).

Art Unit: 2856

12. Claim 2 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4 of copending Application No. 20070289390 in view of US Patent 5,212,993 to William Mayer (Mayer). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a needle having a lumen, a mass flow rate sensor and a vacuum pump in fluid communication with the mass flow rate sensor. The application differs from the patent because it additionally claims an oxygen sensor. Nonetheless, it would have been obvious to one of ordinary skill in the art at the time of the invention to add an oxygen sensor to a package integrity tester, as Mayer did (Mayer, figure 2, sensor 18), because it is conventional to test the oxygen leakage in packaged food (Mayer, column 1, lines 35-40).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 6,935,199 concerns a gas sampler. US Patent 6,324,926 concerns a needle sampling device. US Patent 6,139,801 concerns a gas collector. US Patent 5,433,120 concerns a gas sample collector. US Patent 5,307,696 concerns a needle sampler. US Patent 5,285,678 concerns a seal tester. US Patent 4,133,736 concerns an oxygen content determiner. US Patent 3,849,070 concerns an oxygen content determiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gunnar J. Gissel whose telephone number is (571)270-3411. The examiner can normally be reached on Mon-Fri, 7:30AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571)272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GJG/

4/23/2008

/Hezron Williams/  
Supervisory Patent Examiner, Art Unit 2856